

68959-2

11/19/2013

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

NOV 19 2013

Mr. Micah Reynolds
Regulatory Consultant for,
Veltek Associates, Inc.
15 Lee Boulevard
Malvern, PA 19355-1234

Subject: DECON-AHOL
EPA Registration Number 68959-2
Your Notification Dated October 8, 2013
EPA Received Date October 22, 2013

The notification referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, FIFRA, as amended, to revise the product labeling, is acceptable.

The notification has been made part of the file.

If you have questions concerning this letter, please contact Karen M. Leavy at (703)-308-6237.

Sincerely,

A handwritten signature in cursive script that reads "Marshall Swindell".

Marshall Swindell
Product Manager 33
Regulatory Management Branch I
Antimicrobials Division(7510P)

	United States Environmental Protection Agency Washington, DC 20460	<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number
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Application for Pesticide – Section I

1. Company/Product Number <p style="text-align: center;">68959-2</p>	2. EPA Product Manager <p style="text-align: center;">Marshall Swindell</p>	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) <p style="text-align: center;">DECON-AHOL</p>	PM# <p style="text-align: center;">33</p>	
5. Name And Address Of Applicant (Include ZIP Code) Veltek Associates, Inc. 15 Lee Boulevard Malvern, PA 19355-1234 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____

Section II

<input type="checkbox"/> Amendment – Explain below.	<input type="checkbox"/> Final Printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification – Explain below.	<input type="checkbox"/> Other – Explain Below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

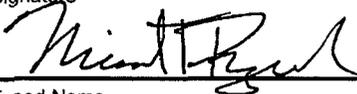
Submission of Label Notification to add packaging specific text, label reference statements, and other non-FIFRA language.

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA. Please confirm receipt with Micah Reynolds: mreynolds@tsgusa.com, via phone (202) 828-8967, or via fax (202) 872-0745.

Section III

1. Material This Product Will Be Packaged In:			
Child Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No * Certification must be submitted	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" No. per Unit Packaging wgt. Container	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(S) Retail Container	5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithographed <input type="checkbox"/> Other _____ <input type="checkbox"/> Pager glued <input type="checkbox"/> Stenciled			

Section IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Micah T. Reynolds, Technology Sciences Group, Inc.	Title Senior Regulatory Consultant	Telephone No. (Include Area Code) (202) 828-8967
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Regulatory Consultant to Veltek Associates, Inc.	
4. Typed Name <p style="text-align: center;">Micah T. Reynolds</p>	5. Date <p style="text-align: center;">October 8, 2013</p>	



Technology Sciences Group Inc.

1150 18th Street, Suite 1000
Washington, DC 20036
Direct: (202) 828-8967
Fax: (202) 872-0745
E-Mail: MReynolds@TSGUSA.com

Micah T. Reynolds
Senior Regulatory Consultant

October 8, 2013

Veltek Associates, Inc.
Submission of Label Notification for:
DECON-AHOL; EPA Reg. No. 68959-2

Mr. Marshall Swindell (PM-33)
Antimicrobials Division (7510P)
Office of Pesticide Programs (**NOTIF**)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, Virginia 22202

Dear Marshall:

Technology Sciences Group, Inc., on behalf of Veltek Associates, Inc. (Veltek), is submitting the enclosed label notification for the above referenced product. The changes being made in the enclosed label are additional text specific to the container to be used, revision and addition of label reference statements, and addition of select non-FIFRA language. These statements are similar to its sister product, DECON-AHOL Aerosol (EPA Reg. No. 68959-4). Please find enclosed the following documents supporting this notification:

- 1) EPA Notification Form (EPA Form 8570-1);
- 2) One redline copy of the proposed label with changes indicated;
- 3) Three (3) clean copies of the proposed label.

If you have any questions or require additional information or clarification, please do not hesitate to contact me by phone at (202) 828-8967 or by e-mail at mreynolds@tsgusa.com.

Sincerely,

Regulatory Consultant to
Veltek Associates, Inc.

Enclosures
CC: P. Deschenes (Veltek)

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IMPORTANT NOTICE
 This product is registered in both the U.S. and Canada
 It has BOTH U.S. and Canadian Labeling
 WHEN USING THIS product in the U.S. follow the U.S. information, where indicated
 WHEN USING THIS product in Canada, follow the Canadian information, where indicated

DECON-AHOL^{®mc}
WFI Formula

[Gamma Irradiated]

For Use in Clean Rooms and Controlled Areas

Hard Surface Disinfectant

Active Ingredient:

Isopropyl Alcohol CAS# 67-63-070.0%

Other Ingredients:

*Water30.0%

Total:..... 100.0%

*USP Water for Injection

KEEP OUT OF REACH OF CHILDREN

DANGER
FLAMMABLE

Keep away from heat or open flame.
Store at room temperature below 48.8°C (120°F)

(Note to reviewer: The following reference statements available for various packaging scenarios.)

See [side] [other] [back] [case label] [panel] [and/or] [package insert] for [first aid] [precautionary statements] [directions for use] [additional precautions] [and] additional product information.
 [Refer to the primary case label for [additional] precautionary statements, directions for use, and additional product information]

[Peel [here] [back] for [Spanish and] additional information]

[See container for lot number and storage expiration date]

US EPA Reg. No.: 68959-2
US EPA Est. No.: 68959-PA-001
Canadian DIN: 02351374

Manufactured by:
 Veltek Associates, Inc.
 15 Lee Blvd.
 Malvern, PA 19355-1234
 Inquiries: (888) 478-3745

In Canada: Distributed by:
 Canada Clean Room
 280 Terance Mathews
 Kanata, On. K2M 2C6

Inquiries: (888) 595-8070

Net Contents: (In Canada XXXX mL or litres) (In US XXX oz or gallons)

FIRST AID	
If in eyes	<ul style="list-style-type: none"> • If splashed in eyes, hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first five minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
If swallowed	<ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Move person to fresh air. • Do not induce vomiting unless told to by a poison control center or Doctor. • Do not give anything to an unconscious person. • Have product container or label with you when calling poison control or doctor, or going for treatment.
If inhaled	<ul style="list-style-type: none"> • Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. • Call poison control center or doctor for treatment advice.
If on skin or clothing	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15 – 20 minutes. • Call a poison control center or doctor for treatment advice.
<p>EMERGENCIES: For Spill/Exposure/Poison Control Emergency Response Service [from the USA and Canada in English, French and Spanish (and 23 other languages)] call CARECHEM24 toll free at 866-928-0789.</p>	

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER: Causes irreversible eye damage. Harmful if swallowed or inhaled. Do not get in eyes or on clothing. Avoid breathing vapor or spray mist. Avoid contact with skin or clothing. Wear protective eyewear such as goggles or face shield, protective clothing and chemically resistant gloves. Wash thoroughly with soap and water after handling, before eating, drinking, chewing gum or using tobacco or using the toilet. Remove and wash contaminated clothing before reuse. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

This product may be irritating to the eyes, skin, gastrointestinal tract and respiratory system. May cause central nervous system depression.

PHYSICAL AND CHEMICAL HAZARDS: **Flammable** liquid and vapor. Keep away from heat or open flame. Exposure to temperatures above 48.8°C (120° F) may cause bursting. Do not mix this product with other chemicals including: acids, oxidizing materials, combustible materials, halogens, peroxides, bases and metal salts.

DIRECTIONS FOR USE
Read the label before using

In the United States: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

In Canada: This product is to be used only in accordance with the directions on the label. It is an offence to use this product in a way that is inconsistent with the directions on the label.

*This product is **NOT** to be used as a terminal sterilant / high-level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high-level disinfection.*

USE: Disinfects and sanitizes clean rooms and controlled areas such as those used in healthcare institutions, biopharmaceutical, pharmaceutical, medical device and diagnostic manufacturing facilities. Use on hard non-porous inanimate surfaces in aseptic filling and gowning rooms, general manufacturing areas, or on machinery, tables, counters, laminar flow benches, floors, walls, carts, shelves made of hard non-porous materials, such as, glass, plastic, vinyl, chrome, and stainless steel. It is compatible with most hard surface materials.

DISINFECTION: Use this product while wearing personal protection. Wear protective eyewear such as goggles or face shield, protective clothing and chemically resistant gloves. Use with adequate ventilation and spray away from eyes and face. DECON-AHOL is ready to use. Do not dilute. Pre-clean surface or item of heavy soil or gross filth before application. Hold can upright 6-8 inches from surface. Thoroughly wet surface with DECON-AHOL and allow to remain wet for a minimum of 10 minutes. Allow surface to air dry, or after 10 minutes wipe dry with sterilized cloth, wiper, if needed.

DECON-AHOL is bactericidal. The results of AOAC Efficacy Tests show that DECON-AHOL is an effective hard surface disinfectant against *Pseudomonas aeruginosa* (ATCC# 15442), *Staphylococcus aureus* (ATCC#6538), and *Salmonella enterica* (ATCC#10708) in the presence of fetal bovine serum organic load in 10 minutes.

SANITIZATION: Use 5 minute contact time on hard, non-porous surfaces (made from: stainless steel, glass, Corian™, laminate flooring, aluminum, pvc, mild steel, polypropylene), in isolators, clean rooms, sterile and controlled areas, gowning rooms and on process lines, gloves, work surfaces, tools and equipment.

DECON-AHOL is an effective sanitizer on inanimate, non-food contact surfaces against *Staphylococcus aureus* (ATCC#6538) and *Klebsiella pneumoniae* (ATCC#4352) in the presence of fetal bovine serum organic load in 5 minutes.

Storage and Disposal

Do not contaminate water, food, or feed by storage or disposal.

Storage: Store in the original container in a dry cool place below 48.8°C (120° F). Absorb spills with inert dry absorbent or sand. Absorb spills with inert material (e.g., dry sand or earth), then place in a chemical waste container.

Disposal: Product and product wastes are toxic. Follow Federal/Provincial/State regulations and Local/Municipal ordinances when disposing of this product. Improper disposal of excess product, spray mixture or rinsate is a violation of Federal/Provincial/State Laws. If these wastes cannot be disposed of by use according to label instructions, contact your Federal/Provincial/State or Local/Municipal environmental control agency for guidance. Contaminated absorbent in drums must be disposed of via an authorized waste disposal contractor. Never place unused product down any indoor or outdoor drain.

Container Disposal: Non-refillable container. Do not reuse this container to hold materials other than pesticides or diluted pesticides (rinsate). Triple rinse container promptly after emptying. Triple rinse as follows: *[(for containers less than 5 gallons) Fill container ¼ full with water and recap. Shake 10 seconds. Follow Pesticide disposal instructions for rinsate disposal. Drain for 10 seconds after flow begins to drip. Repeat two more times.][(for containers greater than 5 gallons) Fill container ¼ full with water. Tip container on its side and roll it back and forth, ensuring one complete revolution for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container on its other end and tip it back and forth several times. Follow Pesticide disposal instructions for rinsate disposal. Drain for 10 seconds after flow begins to drip. Repeat two more times.]* Offer for recycling where available or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

User Information

Date Opened/Operator:

Expiration Date:

Area:

Lot number/ Batch Code: XXXXX

EXPIRY: day/MONTH/year. Once opened use within 90 Days

[MSDS] [No.]: XXXXX [Label No. XXXXX]

[Reorder #]: XXXXX

[Rev XX/XX]

[US Patent 6,123,900, 6,333,006, 6,607,695]

[Made in USA]